EXHIBIT KK

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ETHICON, INC.
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October 19, 1992

To: **Mr. Mark A. Cofone**

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RDCF

Interim report on the physical testing of PROLENE, PVDF, ETHILON & NOVAFIL after seven year subcutaneous implantation in the Beagle Dogs - TEN YEAR BSR STUDY, *ST#E211-92, 85-219*

Attached table shows the physical properties of explanted and baseline samples of size 5-0 Ethilon, Novafil, Prolene and PVDF (N) sutures up to the seven year mark of the ten year BSR study. Implanted Ethilon shows a decrease in breaking strength of 37% at the seven year period compared to the baseline samples. Ethilon samples looked fragile and worn out with spotted surface. Novafil samples show a corresponding decrease of 14% in breaking strength while Prolene and PVDF show no significant change after seven year of implantation. There is a large variation in the elongation results of these samples and all of them showed an increase in the elongation. Young's Modulus values showed a decreasing trend in the range of 50-70% for all the sutures through the seven year period.

Seven year testing conditions were based on the one year and two year data to keep them consistent throughout the study. Tensile testing conditions were 1 in./min crosshead speed (XH) for the Prolene samples and 5 in./min for all other samples with gauge length (G.L.) of 1 inch. If you have any further questions, please feel free to contact me at x2205.

VAgarwal

Vishvaroop Agarwal

Reference: Two year tensile data report from Dr. Peter Moy to Dr. Glenn Graves "10 Year Prolene BSR Study", August 18, 1988.
b:10YR-REP

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RD-CENTRAL FILE

TEN YEAR PROLENE BSR STUDY
7–YEAR DATA SUMMARY

Suture	Dog	Site	Straight Strength (lb)	Elongation (%)	Modulus (psi)
ETHILON	2001	2	1.92 ± 0.03	49.50 ± 3.81	263500 ± 20360
ETHILON*	2008	5	0.89 ± 0.16	25.14 ± 4.10	181500 ± 8866
ETHILON*	2008	1	0.64 ± 0.26	20.73 ± 6.72	149300 ± 25230
ETHILON	2019	5	1.63 ± 0.12	40.12 ± 4.77	298600 ± 47810
ETHILON	2019	6	1.65 ± 0.25	35.76 ± 12.21	244200 ± 12310
Average			1.35	34.25	227420
NOVAFIL	2001	3	1.53 ± 0.14	60.80 ± 3.54	166900 ± 13150
NOVAFIL	2001	6	1.53 ± 0.02	59.20 ± 2.26	182100 ± 13130
NOVAFIL	2007	2	1.49 ± 0.01	56.80 ± 2.38	177000 ± 7476
NOVAFIL	2008	3	1.51 ± 0.02	57.88 ± 3.62	167400 ± 8933
NOVAFIL	2019	1	1.51 ± 0.02	54.60 ± 1.54	191100 ± 4925
Average			1.51	57.86	176900
PROLENE	2001	4	1.58 ± 0.05	80.14 ± 8.15	207700 ± 14672
PROLENE	2001	5	1.61 ± 0.03	80.26 ± 2.07	219600 ± 19430
PROLENE	2007	6	1.62 ± 0.02	79.50 ± 6.41	218925 ± 18508
PROLENE	2007	1	1.61 ± 0.04	76.76 ± 11.63	217275 ± 20455
PROLENE	2008	2	1.54 ± 0.02	70.76 ± 10.21	220000 ± 8305
PROLENE	2019	2	1.61 ± 0.03	78.06 ± 12.46	203125 ± 19402
Average			1.60	77.58	214438
PVDF (N)	2001	1	2.14 ± 0.04	67.66 ± 2.92	163900 ± 8454
PVDF (N)	2007	4	2.13 ± 0.04	67.62 ± 2.56	167600 ± 13220
PVDF (N)	2007	5	2.19 ± 0.06	61.80 ± 1.03	188125 ± 2634
PVDF (N)	2008	4	1.86 ± 0.08	84.80 ± 15.29	131800 ± 11150
PVDF (N)	2019	4	2.13 ± 0.06	64.72 ± 3.04	167000 ± 5115
Average			2.09	69.32	163685

* Looked Worn Out

Untested:

(i) PVDF in Dog#2008 at Site#6 had less than required gage length.

(ii) Ethilon in Dog#2007 at Site#3 looked very fragile, spotted surface and worn out.

Conditions: Tested on Instron 4201 (Series IX) at G.L. of 1 in. and XH Speed of 1"/min for Prolene and 5"/min for all other samples.

ST# E211–92, 85–219

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DATA SUMMARY OF TEN YEAR PROLENE BSR STUDY

	TIME PERIOD (Years)				CHANGE FROM BASELINE (%)		
	0	1	2	7	1	2	7
BREAKING STRENGTH (lb)							
ETHILON	2.13	1.76	1.75	1.35	−17	−18	−37
NOVAFIL	1.76	1.68	1.64	1.51	−5	−7	−14
PROLENE	1.68	1.56	1.64	1.60	−7	−2	−5
PVDF(N)	2.17	2.12	2.16	2.09	−2	−0	−4
ELONGATION (%)							
ETHILON	27	29	25	34	7	−7	26
NOVAFIL	37	41	32	58	11	−14	57
PROLENE	37	37	33	78	0	−11	111
PVDF(N)	34	41	38	69	21	12	103
YOUNG'S MODULUS (Kpsi)							
ETHILON	544	352	449	227	−35	−17	−58
NOVAFIL	369	314	301	177	−15	−18	−52
PROLENE	721	661	677	214	−8	−6	−70
PVDF(N)	330	306	392	164	−7	19	−50

Testing Conditions: G.L. = 1 in. and XH Speed = 1"/min for Prolene and 5"/min for all other samples.
ST# E211−92, 85−219
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